BIOPSY ASSEMBLY

REFERENCES TO RELATED APPLICATIONS

[0001] This application claims the benefit of United States Provisional Patent Application Serial No. 60/433,292, which was filed on December 12, 2002.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] This invention relates to a biopsy device for collecting a biopsy specimen from an anatomical site. More specifically, the subject invention relates to a biopsy device with coaxially positioned cannulas for collecting a biopsy specimen from a bone while simultaneously minimizing trauma to the bone from which the specimen is collected and to tissues adjacent the bone.

2. Description of the Related Art

[0003] Numerous assemblies exist in the art for piercing through a bone to harvest a biopsy specimen of bone marrow therefrom. For example, it is known to advance an access cannula having an introduction needle coaxially positioned therein into a bone to establish an access pathway leading to a predetermined site from which a biopsy specimen is collected. Unfortunately, once the pathway has been defined and the access cannula and needle withdrawn, the pathway must be re-established each time an additional instrument is introduced therethrough, and undergoes additional trauma after the specimen is cut from the site and removed therefrom. Repeatedly inserting instruments through the unprotected

pathway subjects the tissue surrounding the pathway and harvest site to unnecessary trauma.

[0004] Although certain assemblies utilize an access cannulas within which cannulas are coaxially positioned to minimize the need to re-establish the access pathway, such assemblies possess certain limitations. One such assembly utilizes a inner cannula having a distal end defining an interior chamber into which a plurality of threads radially extend. The threads are embedded into the specimen as the specimen is received within the chamber. While the threads may assist in severing the specimen from the remaining tissue at the harvest site and help retain the specimen within the chamber as the cannula is withdrawn, the threads "work" too well, in that the grip the embedded threads place on the specimen makes it difficult to remove from the chamber without compromising the structural integrity of the specimen.

[0005] Other assemblies attempt to simplify the process of harvesting a specimen by incorporating a specialized cutting edge on the distal end of the inner cannula. However, to the extent such a cutting edge is capable of penetrating the bone tissue without breaking or otherwise bending and inflicting additional trauma to the site or specimen, that success is offset by the other components of the assembly, which fail to act in concert with the cutting edge to collect an intact biopsy specimen of sufficient size without sacrificing the access pathway to the harvest site.

SUMMARY OF THE INVENTION AND ADVANTAGES

[0006] The subject invention provides a biopsy assembly for collecting a biopsy specimen from a mass of bone. The assembly includes an inner cannula for

being coaxially positioned within an access cannula and formed to sever a biopsy specimen from the bone and retain the specimen therein. More specifically, the inner cannula extends from a proximal end to the distal end. A swaged portion extends from the distal end for retaining the biopsy specimen. The swaged portion includes a non-deformable sidewall with a frustoconical interior surface that extends radially inwardly at a predetermined angle from the distal end to the biopsy opening for receiving the biopsy specimen therethrough.

[0007] The subject invention also provides a method of collecting a biopsy specimen from a bone in which an introduction stylet is disposed within the access cannula and is then inserted into the bone to establish a harvest site. The stylet is withdrawn, and an inner cannula is inserted within the access cannula. A portion of the inner cannula is swaged to form a non-deformable sidewall having a frustoconical interior surface extending radially inwardly at a predetermined angle from the distal end to converge at a continuous annular cutting edge defining a biopsy opening. The cutting edge severs a biopsy specimen from the harvest site as the cannulas are simultaneously advanced a predetermined distance into the bone. As the method proceeds, the access cannula maintains the tract to the harvest site, which eliminates the need to need to re-establish the tract to the site after the specimen is retrieved. Therefore, once the inner cannula with the specimen therein is removed from the access cannula, the access cannula remains as an open pathway for use in accessing the harvest site to perform other procedures including, but not limited to injecting bone cement into the site. The access and inner cannulas work in concert rather than acting as independent devices in independent steps, thereby reducing the number of steps and minimizing tissue trauma.

[0008] Accordingly, the subject invention overcomes the limitations of the related art by providing a biopsy assembly that not only maintains a protected access pathway to the harvest site for permitting additional procedures to be performed, but also utilizes an inner cannula having a unique distal end for severing and removing a specimen in a manner that minimizes trauma to the specimen and harvest site.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0009] Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

[0010] Figure 1 is an exploded perspective view of a biopsy assembly according to an embodiment of the present invention;

[0011] Figure 2 is a side view of the access cannula and stylet utilized in the assembly of the present invention inserted initially through the cortex of a bone;

[0012] Figure 3 is a fragmentary cross-sectional view of the stylet cap and cannula handle utilized in the present invention;

[0013] Figure 4 is a fragmentary side view of the distal end of the access cannula and stylet initially positioned in the bone;

[0014] Figure 5 is a fragmentary side view of the access cannula, bone and stylet, with the stylet withdrawn from the access cannula;

[0015] Figure 6 is a side view of the inner cannula and the cannula handle;

[0016] Figure 7 is a fragmentary cross-sectional view of the swaged portion of the inner cannula;

[0017] Figure 8 is a fragmentary perspective view of the distal end and swaged portion of the inner cannula;

[0018] Figure 9 is a perspective view of the tool handle being locked to the access cannula handle;

[0019] Figure 10 is a fragmentary side view of the tool handle positioned within the cannula handle;

[0020] Figure 11 is a side view of the inner cannula inserted fully within the access cannula with the swaged portion extending into the harvest site;

[0021] Figure 12 is a fragmentary side view of the distal and open ends of the inner and access cannulas, respectively, fully extended into the bone marrow;

[0022] Figure 13 is a side view of the access cannula and inner cannula with a syringe coupled to the inner cannula;

[0023] Figure 14 is a side view of the inner cannula and partial view of an obturator inserted therein;

[0024] Figure 15 is a fragmentary cross-sectional view of the swaged portion of the inner cannula cutting into the harvest site;

[0025] Figure 16 is a fragmentary cross-sectional view of the swaged portion of the inner cannula severing a specimen from the harvest site; and

[0026] Figure 17 is a fragmentary cross-sectional view of the swaged portion and fragmentary view of the obturator inserted therethrough and removing the specimen therefrom.

DETAILED DESCRIPTION OF THE INVENTION

[0027] Referring to the Figures, wherein like numerals indicate like or corresponding parts throughout the several views, a biopsy assembly for insertion into a mass of bone to collect a biopsy specimen of tissue is shown generally at 20 in Figure 1.

[0028] The assembly 20 includes a cannula handle **22** with a passageway **24** extending therethrough from a support end **26** to a receiving end **28**. The receiving end **28** defines a recess **30**, which is disposed about the passageway **24**. Male luer threads **32** are disposed in the recess **30** about the receiving end **28**. The assembly **20** also includes an access cannula **34** having a proximal end **36** supported in the passageway **24** of the handle **22**. The access cannula **34** extends from the proximal end **36** to an open end **38**. Although the open end **38** is defined by a toothed cutting edge, any suitable cutting edge may be utilized.

[0029] An introduction stylet **40** is also utilized in the assembly **20**. A cap **42** supports the stylet **40**. As is shown in Figures 2 through 4, the stylet **40** is selectively inserted into the passageway **24** and through the access cannula **34** and then used to advance the access cannula **34** into a mass of bone **44** to establish a biopsy harvest site in the bone marrow. The harvest site is shown generally at **46**. The cap **42** has opposed fingers **48** that selectively engage the male luer threads **32** of the cannula handle **22** for guiding the cap **42** into proper alignment within the recess **30**.

[0030] Although the bone **44** shown throughout the Figures is a human vertebrae, the term "bone" as used herein refers to any mass of bone of any

living or non-living organism, regardless of whether the mass is *in situ* and regardless of the origin of the mass of bone.

[0031] The cannula handle **22** and the cap **42** also present a coacting tongue and groove connection **50** for maintaining the cap **42** and stylet **40** in a stationary position relative to the access cannula **34** and cannula handle **22**. The tongue and groove connection **50** engages upon rotation of the cap **42** relative to the handle **22**. As is shown in Figure 3, a plurality of grooves **52** extend radially into the cannula handle **22** within the recess **30**, and a plurality of tongues **54** extend radially from the cap **42**. The tongues **54** engage the grooves **52** upon rotation of the cap **42** within the recess **30**, which in turn interlocks the cap **42** and handle **22**. The cannula handle **22** and cap **42** may alternatively be preassembled for use with the stylet **40** and coaxially positioned within the access cannula **34**. Although any suitable stylet and cannula may be utilized for accessing the bone **44**, the stylet **40** and cannula **34** and respective cap **42** and handle **22** associated therewith are of the type manufactured and sold by Manan Medical Products, Inc.

[0032] Referring now to Figure 4, the stylet **40** is inserted into the passageway **24** and through the access cannula **34** to close the open end **38** thereof. The stylet **40** extends to a distal tip **56** that terminates in a sharp point **58**. The style **40** is inserted through the passageway **24** of the access cannula **34** until the tip **56** extends through the open end **38**. This permits the tip **56** to be introduced into the mass of bone **44** and utilized to advance the stylet **40** and access cannula **34** into the mass **44** to establish the harvest site **46**.

[0033] Although the distal tip of the stylet **40** may have any configuration suitable for piercing the cortex **60** of the bone **44**, the distal tip **56**

shown in Figure 4 includes four beveled facets **62** which converge to define the point **58**. The facets **62** cooperate with the point **58** to bore through the bone **44** in response to rotation of the stylet **40** within the access cannula **34**.

[0034] Referring again to Figure 1, the assembly **20** also includes an inner cannula **66** having a longitudinal axis **67** and extending from a proximal end **68** to a distal end **70**. The inner cannula **66** is selectively inserted through the passageway **24** of the cannula handle **22** and into the access cannula **34**. As is best shown in Figures 7 and 8, a swaged portion **72** extends from the distal end **70**. The portion **72** is uniquely designed to retain a biopsy specimen **74** therein. In particular, the swaged portion **72** features a non-deformable sidewall **76** having a frustoconical interior surface **78** that extends radially inwardly at a predetermined angle "θ_1" from the distal end **70** to a biopsy opening **80**. The opening **80** receives the biopsy specimen **74** therethrough.

[0035] The sidewall **76** also has an exterior surface **82**, and the biopsy opening **80** has an annular cutting edge **84** that radially extends from the longitudinal axis **67**. The exterior surface **82** extends radially inwardly at a predetermined angle "θ_2" from the distal end **70** to the cutting edge **84**. Beveled facets **86** extend between the exterior surface **82** and the cutting edge **84**, which in turn renders the cutting edge **84** sharp. The facets **86** also converge at the cutting edge **84** to define a pair of opposed cusps **88**.

[0036] The manner in which the cutting edge **84** is rendered sharp facilitates cutting into the cancellous tissue in the bone mass **44** and through the trabeculae of the bone marrow at the harvest site **46**. In particular, an increased amount of pressure may be applied at the cutting edge **84** and to the site **46** for

achieving a cleaner, more accurate cut into the bone **44**, while simultaneously minimizing trauma to tissue surrounding the harvest site **46** and preserving the structural integrity of the specimen **74** severed therefrom. Furthermore, the angle at which each facet **86** extends from the cutting edge **84** results in cusps **88** which are sufficiently sharp to pierce the cortex **60**, yet have a profile shallow enough to reduce the likelihood of breaking and becoming embedded in the tissue at the harvest site **46**.

[0037] Although the interior surface **78** of the swaged portion **72** may extend at any angle between the distal end **70** and the biopsy opening **80**, the predetermined angle "θ_1" at which the interior surface **70** extends from the longitudinal axis **67** of the inner cannula **66** is 2°. The exterior surface **82** may extend at any suitable angle between from the distal end **70** to the cutting edge **84**; however, like the interior surface **70**, the exterior surface **82** extends at a 2° relative to the longitudinal axis **67** of the inner cannula **66**. As is shown in Figures 15 and 16, the angle "θ_1"at which the interior surface **70** extends relative to the longitudinal axis **67** creates an increased axial load, or force, "F" on the specimen **74** in the direction shown when the inner cannula **66** is withdrawn from the harvest site **46**. This facilitates separation of the specimen **74** from the site **46**. Once the specimen **74** has been separated from the site **46**, the angle "θ_1" of the interior surface **70** further serves to retain the specimen **74** within the swaged portion **72** until the specimen **74** is removed therefrom through the biopsy opening **80**.

[0038] The frustoconical interior surface **78** and exterior surface **82** are formed by swaging the portion **72**. Swaging is a process in which a stamp, die or other suitable implement is used in conjunction with a hammer or other suitable tool

to bend or shape cold metal. Although the portion **72** is formed by swaging, the portion **72** may be formed using any suitable alternative process.

[0039] A tool handle **94** is connected to the proximal end **68** of the inner cannula **66**. The tool handle **94** has an arcuate shape that fits comfortably and interchangeably within the palm of either hand of a user. The handle **94** is also specifically designed for interlocking engagement with the cannula handle **22**, which maintains the inner cannula **66** in a stationary position relative to the access cannula **34**. As is best shown in Figures 9 and 10, the tool handle **94** includes tongues **96** that are selectively inserted into the grooves **52** in the cannula handle **22** after the inner cannula **66** has been inserted through the access cannula **34** by rotating the tool handle **94** relative to the cannula handle **22** in the direction "D" shown. Interlocking the handles **94** and **22** in this manner enhances a user's ability to simultaneously rotate the coaxially positioned cannulas **66** and **34** and manipulate the same to advance the cutting edge **88** into the mass **44**.

[0040] The tool handle **94** also includes a luer connector **98**. The assembly **20** features a syringe **100**, which is connected to the luer connector **98** and used to apply vacuum to the inner cannula **66**, which in turn helps retain the biopsy specimen **74** within the swaged portion **72**. The syringe **100** includes a plunger **101**. The vacuum is applied by withdrawing the plunger **101** from the syringe **100**. As is best shown in Figures 1, 4 and 17, the inner cannula **66** is withdrawn from the access cannula **34**, and an obturator **102** with a cap **103** disposed on an end thereof is inserted through the inner cannula **66** to remove the biopsy specimen **74** therefrom by advancing the specimen **74** through the biopsy opening **80**.

[0041] Once the inner cannula **66** has been removed, the access cannula **34** may remain in place within the bone mass **44** to maintain an access pathway to the harvest site **46**. This permits other tools, diagnostic instruments and devices to be coupled to the access cannula **34** for performing additional procedures or delivering biomaterials, pharmaceuticals or other therapeutic agents to the harvest site **46**. For example, a bone cement dispenser may be coupled to the male screw threads **32** for dispensing bone cement through the access cannula **34**.

[0042] The subject invention also includes a method of collecting the biopsy specimen **74** of the bone mass **44**. The method includes the step of inserting the introduction stylet **40** through the access cannula **34** to close the open end **38** of the access cannula **34**. The stylet **40** and access cannula **34** are then inserted into the bone **44** to establish the harvest site **46**. The introduction stylet **40** is removed from the access cannula **34**, whereby the access cannula **34** maintains the access pathway to the harvest site **46**.

[0043] The method continues by the portion **72** of the inner cannula **66** to form the non-deformable sidewall **76** having the exterior surface and the frustoconical interior surface **78**, which is to extend radially inwardly at a predetermined angle "θ_1"from the distal end **70** to converge at the continuous annular cutting edge **84** defining the biopsy opening **80**. The inner cannula **66** is inserted into the access cannula **34** until the cutting edge **34** extends through the open end **38**. The access and inner cannulas **34** and **66**, respectively, are advanced a predetermined distance into the bone **44**, whereby the cutting edge **84** severs the specimen **74** from the bone **44** and urges the specimen **74** through the biopsy opening **80** into the inner cannula **66**.

[0044] The final steps are removing the inner cannula **66** from the bone **44** and then removing the specimen **74** from the inner cannula **66**.

[0045] The method is further defined as forming the pair of beveled facets **86** on the sidewall **86** of the inner cannula **66** to extend between the exterior surface **82** and the cutting edge **84** for rendering the cutting edge **84** sharp. Another step involves converging the facets **86** at the cutting edge **84** to define the pair of cusps **88**. Still another step includes connecting the tool handle **94** to the proximal end **68** of the inner cannula **66**, and forming a plurality of tongues **96** on tool handle **94** to extend therefrom.

[0046] The method is further defined by inserting the inner cannula **66** through the passageway **24** of the cannula handle **22** carried by the access cannula **34**. The tool handle **94** is then rotated relative to the cannula handle **22** to engage the tongues **96** with the complementary grooves **52** on the cannula handle **22** to thereby retain the inner cannula **66** within the access cannula **34**. Still another step involves connecting the syringe **100** to the luer connector **98** of the tool handle **94** and applying the vacuum to the inner cannula **34** for retaining the biopsy specimen **74** in the inner cannula **34**.

[0047] Obviously, many modifications and variations of the present invention are possible in light of the teachings set forth above. The invention may be practiced other than as specifically described within the scope of the claims. Furthermore, the foregoing description of the preferred embodiment of the invention and the best mode for practicing the invention are provided for the purpose of illustration only and not for the purpose of limitation the invention being defined by the claims.